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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,829	10/30/2003	Mark R. Kreitz	SPS 102/105	1879
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PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			EXAMINER DICKINSON, PAUL W	
			ART UNIT 1609	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/696,829

**Applicant(s)**

KREITZ ET AL.

**Examiner**

Paul W. Dickinson

**Art Unit**

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

### DETAILED ACTION

Applicant is advised the Examiner assigned to this application has changed. The Examiner assigned to this application is **Paul W. Dickinson**, whose contact information appears at the end of this correspondence.

### *Election/Restrictions*

Applicant's election with traverse of Group II (Instant Claims 11-29) and the following species elections listed below in the reply on 1/22/2007 and are acknowledged.

- 1) an agent: small-molecule drugs
- 2) a bioadhesive enhancing agent: bioadhesive organic molecules
- 3) a dispersant: polyvinyl pyrrolidone
- 4) a surfactant: TWEENS®
- 5) an excipient: a tableting agent
- 6) a polymer: poly(lactic acid)

The use of the trademark TWEENS® has been noted. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

In the reply on 1/22/2007, Applicant argues that Groups II and III should be grouped together (p 6, ln 13 to p 7, ln 9). The Examiner does not find the argument

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persuasive. Inventions II and III are related as product and a process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). Claim 11 defines a formulation comprising a population comprising at least at least 95% nanoparticles of a therapeutic, diagnostic or prophylactic agent having a diameter of less than one micron. Applicant argues that claim 11 requires the inclusion of a therapeutic, diagnostic or prophylactic agent, which can only be used in a method requiring the step of administering the formulation to a patient. Examiner finds, however, that the product as claimed can be used in a materially different process. Burrell et al disclose a formulation comprising a population comprising nanoparticles of a therapeutic agent, where the therapeutic agent is gold nanoparticles (see Burrell et al, WO 02/09729, 2/7/2002; p 1, ln 13 to p 2, ln 8). A formulation comprising gold nanoparticles can be used in a materially different process other than administration to a patient, such as use in thin film deposition for electronic devices or use as catalysts in asymmetric dehydroxylation reactions (see Brust et al, Some recent advances in nanostructure preparation from gold and silver particles: a short topical review, *Colloids and Surfaces A: Physicochemical and Engineering Aspects*, 2002, 202, 175-186; p 183, col 1 ln 39-44 and p 183, col 2, ln 46-48). The requirement is still deemed proper and is therefore made FINAL.

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Instant Claims 1-10, 30-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11-12, 14, 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "a formulation comprising a population comprising at least 95% nanoparticles... having a diameter of less than one micron" in Claim 11 is vague and indefinite. It is unclear if said population constitutes some or all of the total population of nanoparticles in the formulation. The population, as claimed, could only constitute, say, 2% of the total number (or volume) of nanoparticles in the formulation, the other 98% having a different diameter range.

The phrase "small-molecule drugs" in Claim 12 is vague and indefinite. Small-molecule drugs could reasonably encompass drugs as small as single protons to drugs as large as proteins with molecular weights of over 10,000 daltons. There is no definition or even examples of what Applicant means by "small-molecule drugs" given in the instant application.

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The phrase "sufficiently hydrophobic to be insoluble in water" in Claim 14 is vague and indefinite. Sufficiently is a relative term and its use here is unclear. Furthermore, other factors besides hydrophobicity affect a given compound's solubility in water, such as temperature and pH. There is no definition or even examples of what Applicant means by "sufficiently hydrophobic to be insoluble in water" given in the instant application.

The phrase "drug loading of (up to 70%)/(between approximately 30 and 70%) by weight" in Claims 27 and 28 is vague and indefinite. It is unclear whether weight here refers to the nano or micro particle weight, the weight of the total formulation, or something else. There is no definition or even examples of what Applicant means by "weight" given in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Instant Claims 22-29 rejected under 35 U.S.C. 102(b) as being anticipated by Gittins et al (Gittins et al, Biological and Physical Applications of Water-Based Metal Nanoparticles Synthesized in Organic Solution, ChemPhysChem, 2002, 1, 110-113) Gittins et al disclose a nanoparticulate metal formulation (p 110, col 2, ln 33 to p 111, col 1, ln 2). Claim 22 is directed to a nano or micro particulate formulation. Because "for oral administration of a taxane..." is an intended use, it does not limit the claim and is herein not given patentable weight. Therefore, any nano or micro particulate formulation disclosed prior to the time of the invention anticipates Claims 22-28.

Claim 29 is drawn to a nano or micro particulate formulation further comprising a surfactant or excipient. The formulation disclosed by Gittins et al further comprises water (p 111, col 1, ln 1).

Instant Claims 11-15, 17-18, 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Sharma et al (Sharma et al, Novel Taxol Formulation: Polyvinylpyrrolidone Nanoparticle-Encapsulated Taxol for Drug Delivery in Cancer Therapy, Oncology Research, 1996, 8, 281-286).

Claim 11 is directed to a formulation comprising a population comprising at least 95% nanoparticles of a therapeutic, diagnostic or prophylactic agent having a diameter of less than one micron. Sharma et al discloses a formulation comprising Paclitaxel-containing polyvinylpyrrolidone nanoparticles wherein at least 95% of the nanoparticles have a diameter of less than one micron (p 282, col 1, ln 14-15; p 283, col 1, ln 40-46; Figure 2).

Claim 12 is directed to a small-molecule drug. Paclitaxel is a small-molecule drug.

Claims 13-14 are directed to water-insoluble agents. Paclitaxel is a water-insoluble agent.

Claim 15 is directed to a formulation wherein at least 99% of the nanoparticles have a diameter of less than one micron. At least 99% of the nanoparticles in the formulation disclosed by Sharma et al have a diameter of less than 1 micron (see p 283, ln 40-46; Figure 2).

Claims 17 is directed to a formulation further comprising a dispersant. Claim 18 is directed to a formulation further comprising a polymer. The formulation disclosed by Sharma et al comprises polyvinylpyrrolidone nanoparticles (p 282, col 1, ln 14-15), which is both a dispersant and a polymer.

Claim 21 is directed to a product-by-process. The formulation disclosed by Sharma et al anticipates Claim 21. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim 22 is directed to a formulation for administration of a taxane. Although the formulation disclosed by Sharma et al was administered to mice intravenously (p 283,

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col 1, ln 20-22), the formulation still anticipates Claims 11-15, 17-18. As noted above, “for oral administration of a taxane...” in Claim 22 is an intended use and does not limit the claim. It is noted, however, that the formulation disclosed by Sharma et al could be used to make a final product for the oral administration of a taxane, and therefore be “for oral administration of a taxane...”.

Claim 23 is directed to a formulation wherein the taxane is paclitaxel. As noted above, “for oral administration of a taxane” is an intended use and is given no patentable weight. The formulation disclosed by Sharma et al does, however, include paclitaxel (p 282, col 1, ln 14-15).

Claim 24 is directed to a formulation wherein the taxane is docetaxel. Sharma et al do not disclose a formulation wherein the taxane is docetaxel. As noted above, however, “for oral administration of a taxane” is an intended use, and is given no patentable weight. The formulation disclosed by Sharma et al thereby anticipates Claim 24, which only limits the intended use.

Claims 25 and 26 are drawn to a formulation wherein 90% of the nanoparticles have a diameter less than 5 microns (Claim 25) or 1 micron (Claim 26). Sharma et al disclosed a formulation wherein over 90% of the nanoparticles have a diameter of less than 1 micron (see p 283, ln 40-46; Figure 2).

Claims 27 and 28 are drawn to a formulation wherein the taxane is present in a drug loading of up to 70% by weight (Claim 27) or between approximately 30 and 70% by weight (Claim 28). As noted above, Applicant's use of the term “weight” is indefinite here. The Examiner is interpreting “weight” to mean the weight of the total formulation.

Sharma et al disclose a formulation that is 0.3% by weight of the total formulation (p 282, col 2, ln 25-27). "Approximately 30%" in Claim 28 encompasses 0.3%.

Instant Claim 29 is drawn to a formulation comprising a surfactant or excipient. The formulation disclosed by Sharma et al comprises water (p 282, col 2, ln 20-23).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al (see above) in view of Santos et al (US 6,197,346). Sharma et al discloses a formulation comprising Paclitaxel-containing polyvinylpyrrolidone nanoparticles (p 282, col 1, ln 14-15). Sharma et al does not disclose a formulation further comprising a bioadhesive enhancing agent. Santos et al discloses the benefits of using bioadhesive enhancing agents in particulate formulations (col 1, ln 17-26). One skilled in the art at the time of the invention would have been motivated to take the formulation disclosed by Sharma et al and add a bioadhesive enhancing agent, giving the instant invention.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PWD

  
CECILIA TSANG  
SUPERVISORY PATENT EXAMINER